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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/050,902 | 01/18/2002 | Wolfgang A. Renner | 1700.0190004/BJD/SJE | 7792 |
| 26111 | 7590 | 11/17/2005 | EXAMINER | |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005 | | | | MOSHER, MARY |
| | | ART UNIT | | PAPER NUMBER |
| | | 1648 | | |

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/050,902 | RENNER ET AL. |
| | Examiner | Art Unit |
| | Mary E. Mosher, Ph.D. | 1648 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 August 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 220-272,275-332 and 335-465 is/are pending in the application.
- 4a) Of the above claim(s) 230-237, 245-247, 250-257, 259-267, 277-332, 335-354, 372-379, 387-389, 409-411, 419-458 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 220-229,238-244,248,249,258,355-371,380-386,390-408, 412-418, and 459-465 is/are rejected.
- 7) Claim(s) 268-272,275,276 and 412-418 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
- 1. Certified copies of the priority documents have been received.
 - 2. Certified copies of the priority documents have been received in Application No. _____.
 - 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Response to Amendment

In response to the amendment filed 8/29/2005, the rejection under 35 U.S.C. 103(a) is withdrawn.

Election/Restrictions

Claims 230-237, 245-247, 250-257, 259-267, 277-332, 335-354, 372-379, 387-389, 409-411, 419-458 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/26/2003. The remainder of the claims have been examined for 35 USC 112 compliance to the extent that they read upon the elected species, and to the extent required to determine if the generic claims are allowable.

Claim Rejections - 35 USC § 112

Claims 220-229, 238-244, 248, 249, 258, 355-371, 380-386, 390-408, 459-465 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the self-antigen species VEGFR2, IL5, IL13, and eotaxin (as allowed in copending application 10/289454), does not reasonably provide enablement for the full scope of self antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The generic claims embrace a multitude of species of self antigens. The only disclosed use for all of the species is the prevention or treatment of diseases or disorders where the self product is suspected of

involvement. The lists of diseases and disorders to be treated with self antigens include a very broad range of different conditions, and a number of conditions where prevention or treatment is notoriously difficult, such as systemic lupus erythematosus (SLE), rheumatoid arthritis, multiple sclerosis, and Alzheimer's disease. The list also includes diabetes, where an immune response against the self-antigen would be reasonably expected to exacerbate the autoimmune disease rather than treat it. Therefore, one skilled in the art would have reason to doubt assertions that all of the species embraced in the genus could be used in prevention or treatment without additional guidance. Considering the broad scope of the claims, the limited teachings in the specification, and the absence of working examples of prevention or treatment of diseases or disorders for many of the species recited in the claims, it is concluded that undue experimentation would be required to use the full scope of the claimed products in the manner suggested in the specification.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 220-229, 238-242, 244, 248, 249, 258, 355-371, 380-384, 386, 390-408, 412-418, 459-465 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 2 5-8 12-20 22 25-32 35-40 42-45 65-67 69 74-87 89 95-120 of copending Application No. 10/289454. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the previously allowed claims drawn to IL5, IL13, or eotaxin array particles. This rejection would also be applied to some of the claims withdrawn from consideration, should they be rejoined.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 268-272, 275, 276, 412-418 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/14/05

Mary Mosher
MARY E. MOSHER, PH.D.
PRIMARY EXAMINER